

(19) **FEDERAL REPUBLIC
OF GERMANY**

**GERMAN
PATENT OFFICE**

(12) **Patent Specification**
(10) **DE 196 26 924 C 2**

(51) Int. Cl.⁶:
A 61 M 16/00
A 61 B 5/08
G 05 D 11/035

(21) File number: 196 26 924.5-44
(22) Date of filing of the application : July 4, 1996
(43) Publication date of the application: January 8, 1998
(45) Publication date of the grant of patent: August 19, 1999

DE 196 26 924 C 2

Oppositions may be lodged against the patent within 3 months from the date of the publication of the grant of the patent.

(73) Patent holder:
Epazon B.V., Rotterdam, NL

(75) Representative:
Patent Attorneys Sternagel & Fleischer, 51429 Bergisch
Gladbach

(72) Inventor:
Prof. Dr. Dr. Burkhard Lachmann, Rotterdam, NL;
Rajan, N. Govinda, Huizen, NL

(56) Patents examined in evaluating patentability:
DE 34 22 066 C2
DE 34 13 037 C2
DE 34 12 118 A1
US 41 27 121
WO 87 01 599

(54) Device for dispensing a respiratory gas

(57) Device for supplying respiratory gas for mobile use with at least one respiratory gas source (4), a control device (12) for the respiratory gas flow and a gas delivery system (6) for a controlled respiratory gas flow, where the gas delivery system (6) is connectable to at least one oxygen source (16), characterized by the fact that the respiratory gas source includes a fan driven by an electrical motor (4).

[figure]

Description

The invention relates to a device to supply a respiratory gas with at least one respiratory gas source, a control device for the respiratory gas flow and a gas delivery system for a controlled respiratory gas flow, where the gas delivery system is connectable to at least one oxygen source according to Claim 1.

Such devices are known both for ambulant emergency use and for stationary clinical use.

The respiratory gas source in stationary clinical use is normally a central supply of compressed air and/or oxygen with appropriate connecting points in the patient treatment and hospital rooms. The device itself is generally movable on rollers and has appropriate connecting lines allowing the device to be connected to the central respiratory gas source.

Simpler devices are normally used in ambulant emergency applications, where regular pressurized bottles for compressed air and/or oxygen serve as the respiratory gas source. The gas contained in the pressurized bottles is normally pressurized to about 200 bars.

In order to have a sufficient respiratory gas supply for at least one trip to the hospital, a compressed-gas bottle with a volume of 10 liters is required as a minimum. Because a full pressurized gas bottle is very bulky and heavy in particular, such devices are practical only for ambulant emergency use in motor vehicles or in a helicopter, for example.

In stationary applications a mixture of compressed air and oxygen is normally used as respiratory gas. Since with such a device, oxygen is almost always added in ambulant emergency use, two pressurized bottles are required as respiratory gas source, namely a compressed-air bottle and an oxygen bottle, adding further to the weight. In order to avoid such extra weight it is also known to take along only one oxygen bottle and to mix outside air with the oxygen from the pressurized container by designing flow paths that pass through a Venturi nozzle and to use this as respiratory gas.

The known devices also feature a mechanical or electronic control device allowing the respiratory gas flow to be controlled according to the required respiratory frequency.

One such device, for example, is known from WO 87/06142. The device described therein includes a display unit for monitoring the breathing activity of the patient. Right at the beginning of each inhalation the patient receives a volume pulse of oxygen. If the patient breathes irregularly or is not able to breathe spontaneously, the device supplies a continuous flow of oxygen.

Another device is known from EP-A-324 275, which includes a breathing apparatus and a breathing synchronization device. The device is intended to be used when a patient stops breathing, allowing for respiratory gas to be supplied to the patient from the breathing apparatus at specified intervals after the beginning of inhalation or exhalation. The synchronization device is connected to a display unit to monitor the breathing. The display unit records the physical impedance, electromyograms, chest movements and the like.

These known systems work satisfactorily as long as the patient is relatively healthy and the lungs are in relatively good condition. However, many patients are in bad condition or have atelectatic lungs, i.e. they do not fill completely with air, with the result that the oxygen administered at the beginning of the inhalation has little effect, if any. If a continuous flow of oxygen is administered for longer periods, the effect will be the opposite of that intended by the device, namely, to economize oxygen.

The purpose of the present invention is therefore to improve on the known device for supplying respiratory gas, in particular as far as oxygen consumption is concerned.

This purpose is achieved in the invention by a device of the type described above, which is characterized by the fact that the respiratory-gas source includes a mechanically driven fan. By designing the device according to the invention it is no longer necessary to transport large compressed-air bottles. With the device according to the invention, a 1-liter bottle is sufficient to supply a patient with the necessary oxygen for about 3 hours. Thanks to the small, handy 1-liter bottle, mobile operation of such a device becomes possible, in particular for ambulant use. A permanent installation in the vehicle is no longer required. This makes it possible to use such device also in other first-aid vehicles such as ambulances. With the help of a mechanical motor, the device according to the invention can be operated practically anywhere there is a power supply. When batteries are used it is even possible to design a device according to the invention in such a way that it can run for significant lengths of time with no external power supply. This could be useful when rescuing an injured person from a site inaccessible to motor vehicles, for example.

However, a drive system other than an electrical motor, e.g. a compressed-air drive, is also feasible. This is useful whenever the device is to be used in places where a compressed-air supply is available for other purposes but where the compressed air does not have the purity required for medical applications, e.g. when it contains oil. This may be the case, for example, when such devices are carried in large ambulances or on overseas airline flights.

In order to be able to use the device as a continuous breathing apparatus even when a patient stops breathing altogether it is useful if the device in operation can deliver a dynamic pressure more than 400 Pa greater than the ambient pressure, in particular about 600 Pa, on the receiver side of the gas delivery system.

Another such device according to the invention of the type can be used for respiration at Positive-End Expiratory Pressure (PEEP), while still being compact and easy to handle, provided the device also includes a backflow device and a valve connected to the control device for the respiratory gas flow, where the valve in a first operating position opens up most of the cross section of the gas delivery system in the direction of its receiver side and in a second operating position obstructs most of the cross section of the gas delivery system and/or connects it to the outside and where the valve in the first operating position obstructs most of the cross section of the backflow device and in a second operating position opens up most of it.

In order to separate the inhalation and exhalation flows as thoroughly as possible it is useful for the backflow to be connected to the gas delivery system near the receiver side.

In order to be able to use the breathing techniques PEEP and CPPV with minimal equipment it is useful for the device in operation to deliver a dynamic pressure higher than the ambient pressure at the receiver side of the gas delivery system whenever the valve is in the second operating position, in particular if in the process the dynamic pressure above the ambient pressure is regulated by a pressure control valve in the backflow device, where it is useful for the dynamic pressure to be approximately 50-200 Pa.

For minimal oxygen consumption it is useful for the device to include a dosing device to ensure the required supply of additional oxygen to the respiratory gas and for the control device to control the dosing device.

To ensure optimal coordination of the various components and to compensate for losses caused by leaks such as from a breathing mask, it is useful for the device to have at least one measuring system to determine at least one parameter of the supplied gas, where at least one such measuring system influences the control device.

The purpose is further achieved by a device of the type mentioned above which is characterized by at least one measuring system to determine at least one parameter of the supplied gas, where at least one such measuring system influences the control device, in particular by controlling the dosing device for the required supply of additional oxygen to the respiratory gas.

By designing the device of the type mentioned above in accordance with the invention it becomes possible to adjust the supply of respiratory gas as a function of the condition of the patient and the patient's needs, in particular the addition of oxygen to the respiratory gas.

Preferably, at least one such measuring system includes a gas-flow meter and/or a gas-pressure meter and/or a device for measuring the gas concentration, in particular the oxygen concentration, in the supplied gas.

The purpose is further achieved by a method for supplying respiratory gas to live organisms which is characterized by measuring at least one parameter of the supplied gas and adding a certain amount of oxygen as a function of at least one such measured parameter. This allows for optimization of oxygen consumption relative to the additional oxygen supply that is medically necessary.

Preferably a certain amount of oxygen is added after detection of a specified value for at least one such parameter, in particular at a certain time after detecting such a value, in particular at a certain time after detecting the beginning of the inhalation phase.

In an advantageous embodiment of the method the latter is characterized by the fact that the addition of a certain amount of oxygen is proportional to the maximum value of the respiratory gas flow and/or the respiratory gas pressure in a breathing cycle, in particular that the maximum value of the respiratory gas flow and/or the respiratory gas pressure is determined as the maximum value of the respiratory gas flow and/or the respiratory gas pressure in a previous breathing cycle, in particular the average of the maximum values of a certain number of prior breathing cycles.

Particularly low oxygen consumption can be achieved if the addition of a certain amount of oxygen to the respiratory gas is made dependent on the detected oxygen concentration level in the exhaled gas, in particular if the duration of the oxygen dispensed by the oxygen source is determined as a function of the detected oxygen concentration level in the exhaled gas.

Preferably the method is characterized by the use of a device according to the invention.

The additional respiratory gas supply to the patient can be ascertained on the basis of the parameter of the supplied gas flow detected by the measuring system. When the lungs are sufficiently open, with all dispensed breathing gas being transported to the air vesicles, oxygen is supplied to the patient in the form of pulses. Depending on the condition of the patient's lungs, the oxygen can be dispensed shortly after the beginning of inhalation or after a certain delay, e.g. if the lungs are very atelectatic or have collapsed. The expression "positive gas pressure" is used here for any pressure above a certain specified base pressure (atmospheric pressure or artificial ventilation pressure with positive-end expiratory pressure/PEEP) after spontaneous or forced inhalation. In contrast, the beginning of spontaneous inhalation is detected by a reduction in gas pressure.

In this specific time sequence oxygen replaces nitrogen and accumulates in the air vesicles after 1 or 2 minutes of artificial ventilation.

In the process it is unimportant whether the patient is able to breathe spontaneously or not. The oxygen is supplied as a function of the detected parameter. This embodiment of the invention may be used with practically all artificial ventilation and respiratory assistance systems, either through integration into the system or as an external accessory.

If the invention is used in connection with breathing assistance device supplying the patient with air or another respiratory gas during inhalation, a certain time delay in dispensing the oxygen from the oxygen source may be of advantage. The time delay can be set by a doctor on the device but preferably it is made dependent on the conditions of the lungs. The time delay may be determined, for example, as the average time until a certain percentage of a maximum value over a specified number of breathing cycles is reached, or depending on the constitution, the suppleness and functional residual capacity of the lungs.

The invention is explained below in greater detail by using the sample embodiments shown in the illustrations, namely:

Fig. 1 shows a schematic illustration of a device according to the invention

Fig. 2 shows a block diagram of another embodiment according to the invention of the device,

Fig. 3 shows a diagram with the device operating in a first operating mode and

Fig. 4 shows a diagram with the device operating in a second operating mode.

Fig. 1 shows a device 1 according to the invention for supplying a respiratory gas which can be connected to a patient 2. In the process purified air is taken in and conveyed from the outside via a suitable filter 3 by a mechanically driven fan 4, with the fan 4 serving as the respiratory gas source. A regular compressed-gas source may also serve as the respiratory gas source.

The volume flow conveyed by the fan 4 into a flow line 6 as gas delivery system and/or the pressure built

up in the gas delivery system 6 is adjustable via a valve 5. The valve 5 can assume at least 2 operating positions. In a first operating position of the valve 5 the latter opens up most of the cross section of the gas delivery system 6 in the direction of the receiver side 7. In a second operating position the valve 5 obstructs the cross section of the gas delivery system 6 completely or partially and/or connects the gas delivery system 6 to the outside, i.e. the gas delivery system 6 is vented.

The receiver side 7 of the gas delivery system 6 serves to connect the device 1 to the patient 2 and may e.g. be designed as a tubular device. It is also useful to integrate into the receiver side 7 a flow-rate meter 8 as gas flow meter.

In order to be able to use artificial ventilation, which is particularly advantageous for respiration in case of atelectatic lungs and to prevent the lungs from collapsing during exhalation against an excess pressure (PEEP/CPPV), it is useful to connect a line 9 as backflow device to the receiver side 7 of the gas delivery system 6.

In order to be able to set the valve 5 according to the spontaneous or controlled breathing of the patient 2, it is useful to also integrate a gas pressure meter 10 into the receiver side 7 of the gas delivery system 6.

The line 9 may contain a pressure relief valve 11 through which the line 9 vents in case a critical pressure is exceeded. Such a pressure relief valve 11 serves as a safety valve in case the valve 5 fails, particularly in its first operating position.

The signals of the measuring devices such as the rate-of-flow meter 8 or the gas pressure meter 10 are fed into a control device 12 that sends a control signal at least to the valve 5. An actuator 13, which may be a stepper motor electromagnet, is used for the purpose. Also, the actuator 13 can send feedback to the control device 12 regarding the position of the valve 5. The control device 12 may also control the fan 4, e.g. in order to minimize the power consumption of the device 1.

The valve 5 influences both the gas flow in the gas delivery system 6 and the backflow device 9. Downstream from the valve 5 a pressure control valve 14 is mounted at the end of the backflow device 9 which sets the desired excess pressure in the backflow device 9 against which the patient 2 is required to exhale. The pressure set via the pressure control valve 14 may be changed as needed directly or via the control device 12 and the corresponding actuator in the pressure control valve 14 in accordance with the medically desirable settings.

In order to make sure, above all in case the device 1 fails, that the patient 2 when inhaling is not supplied with previously exhaled respiratory gas, the direction of the gas flow can be forced e.g. via one non-return valve 15 each in the gas delivery system 6 and the backflow device 9. The non-return valves 15 may be e.g. conventional butterfly valves. Fig. 1 also shows the connection of an optional oxygen source 16 used to enrich the respiratory gas with oxygen. The details of such an arrangement with an oxygen source 16 are described below.

Fig. 2 shows a device 1 for dispensing a respiratory gas in accordance with a further development of the device according to the invention. To show precisely how it functions, a patient 2 is shown connected to the device 1. The shown device 1 includes a respiratory gas source, which either may contain a fan 4, as described above, or may take the form of a conventional breathing assistance device or respiration device. The breathing assistance device may e.g. be a stationary hospital device with all known particulars, e.g. volume and pressure control as well as patient monitor. Accordingly, the respiratory gas may be supplied in the traditional way via a central compressed-gas supply or pressurized bottles.

The shown device 1 also includes a rate-of-flow meter 8, a pressure meter 10, a control device 12 and an oxygen source 16. The control device 12 is connected to a control valve 17 as dosing device for measuring the amount of oxygen to be supplied. The control valve 17 is integrated into a gas line 18 connecting the oxygen source 16 to a gas delivery system 6 in the form of a tubular system. Also, a measuring device 19 for the oxygen concentration is located at the receiver side 7 of the tubular system 6.

The breathing assistance device 4 is connected to the patient 2 via a tubular system 6. The tubular system 6 includes a tube for inhalation and may be connected also to another tube 9 for exhalation. The use of an additional tube 9 for exhalation essentially depends on the type of the breathing assistance device 4 that is used. Only one tube is normally used for inhalation in portable devices for traumatology and for home use. The patient exhales directly into the ambient air through a valve. The tubular system 6 contains the rate-of-flow meter 8 and the pressure meter 10 to measure the gas volume flow to the patient 2 and the airway pressure in the patient 2. The measured values are transmitted to the control device 12 which controls the breathing assistance device 4 according to the measured values.

The control device 12 also controls the control valve 7 for adding oxygen from the oxygen source 16 to the patient 2 via a gas line 18 and the tubular system 6.

Fig. 3 shows a diagram representing the volume flow and pressure over two breathing cycles. The diagram shows how the device works with respect to volume control.

First the patient is supplied with a first inhalation volume flow 20A. The volume flow 20A is constant. After a short pause the first exhalation 20B takes place which in turn is followed by a second inhalation flow 20C and another exhalation 20D.

As can be seen from the diagram, the pressure P in the airways 22A increases while respiratory gas is supplied to the patient. When the flow stops the pressure starts to drop and falls further during exhalation 22B. The pressure drops to the atmospheric pressure or a higher pressure level if respiration takes place at positive-end expiratory pressure (PEEP). However, respiration at negative-end expiratory pressure (NEEP) is also possible. The same process is repeated during the second inhalation 22C and the second exhalation 22D.

In patients with Acute Respiratory Distress Syndrome (ARDS) closed respiratory cycles have no uniform time constants, which means variable characteristics in terms of flow resistance and suppleness. If oxygen is applied directly after the inhalation begins, vital parts of the lungs may possibly

still not be vented properly. In order to improve oxygen supply to the lungs using a minimum of oxygen, the supply of oxygen is delayed until the lungs are sufficiently open as shown by the pressure curve in 22A in Fig. 3. When a certain pressure P in relation to the maximum pressure is reached, oxygen is supplied, as shown by the black bars 24 and 26.

Fig. 4 essentially shows the same for a pressure-controlled operating mode. A first inhalation 32A and a second inhalation 32C takes place at a specified pressure level. A first and second exhalation 32B and 32C takes place at positive-end expiratory pressure (PEEP). The pressure pulse 32A specifies the inhalation flow 30A to the patient. The inhalation flow 30A is large at the beginning of the inhalation and then drops until exhalation 30B sets in. A second inhalation 30C and exhalation 30D takes place accordingly.

In this operating mode oxygen is supplied only when the gas flow reaches a specified percentage Φ_1 of the maximum gas flow indicated in Fig. 4 by black bars 34 and 36.

The measured maximum values in one breathing cycle or the calculated averages of several prior breathing cycles may be used as reference maximum values. When the gas flow or pressure reaches the percentage of the reference maximum specified by the doctor, oxygen is supplied. A combination of volume flow and pressure may also be used.

Instead of using certain volume flow or pressure values the doctor may also input a certain time delay or it may be calculated by the control device 12. As can be seen from Figures 3 and 4, oxygen is supplied after a certain time delay. The magnitude of this time delay is determined by the condition of the lungs and corresponds to a time sequence that ensures the best efficiency for supplying oxygen. Through lung measurements the physician may specify a certain time delay for supplying oxygen after the beginning of the inhalation. Alternatively the control device 12 may be programmed to calculate the time delay by measuring the volume flow and pressure. For example the control device can calculate an average for the time delay over a number of breathing cycles as shown in Figures 3 and 4 and then use the time delay that it calculated. For relatively healthy patients the time delay may also be set to a fixed value without adjustment to the individual lung condition, e.g. for device used in traumatology.

The same operating mode may be used for other operations of a breathing assistance device or respiration device, e.g. in case of breathing support. Also, respirators operated manually by medical personnel may be equipped accordingly.

Another possible actuating variable is the duration of the oxygen supply. This is controlled in such a way that it is long enough to supply oxygen to the appropriate parts of the lung, i.e. to the airways and air vesicles, but not so long that oxygen is exhaled again unused. This can be achieved by measuring the oxygen concentration in the exhaled air, e.g. with the oxygen concentration meter 19 in Fig. 1 or by way of the oxygen concentration of the blood (not shown).

Such highly developed breathing assistance devices or respirators can be equipped accordingly, but other arrangements are possible.

Patent Claims

1. Device for supplying respiratory gas for mobile use with at least one respiratory gas source (4), a control device (12) for the respiratory gas flow and a gas delivery system (6) for a controlled respiratory gas flow, where the gas delivery system (6) is connectable to at least one oxygen source (16), characterized by the fact that the respiratory gas source incorporates a fan (4) driven by an electrical motor.
2. Device according to Claim 1, characterized by the fact that the device in operation can deliver dynamic pressure 400 Pa greater than the ambient pressure on the receiver side (7) of the gas delivery system (6).
3. Device according to Claim 2, characterized by the fact that the dynamic pressure is approximately 600 Pa.
4. Device according to the general concept of Claim 1 or one of the previous Claims, characterized by the fact that the device also features a backflow device (9) and a valve (5) connected to the control device (12) for the respiratory gas flow, where the valve (5) in a first operating position opens up most of the cross section of the gas delivery system (6) in the direction of its receiver side (7) and in a second operating position obstructs most of the cross section of the gas delivery system (6) and/or connects it to the outside, and where the valve (5) in the first operating position obstructs most of the cross section of the backflow device (9) and in a second operating position opens up most of it.
5. Device according to Claim 4, characterized by the fact that the backflow device (9) is connected to the gas delivery system (6) near the receiver side (7).
6. Device according to one of the Claims 4 or 5, characterized by the fact that the device in operation delivers a dynamic pressure higher than the ambient pressure at the receiver side (7) of the gas delivery system (6) whenever the valve (5) is in the second operating position.
7. Device according to Claim 6, characterized by the fact that the dynamic pressure above the ambient pressure is regulated by a pressure control valve (14) in the backflow device (9) whenever the valve (5) is in the second operating position.
8. Device according to Claim 6 or 7, characterized by the fact that the dynamic pressure is about 50-200 Pa above the ambient pressure whenever the valve (5) is in the second operating position.
9. Device according to one of the previous Claims, characterized by including a dosing device (17) for the addition of extra oxygen to the respiratory gas and a control device (12) that influences the dosing device (17).
10. Device according to one of the previous Claims, characterized by having at least one measuring system (8,10, 19) for determining at least one parameter of the supplied gas flow, where at least one such measuring system (8, 10, 19) influences the control device (12).
11. Device for dispensing a respiratory gas with at least one respiratory gas source (4), a control device (12)

DE 196 26 924 C2

for the respiratory gas flow and a gas delivery system (6) for the controlled respiratory gas flow, where the gas delivery system (6) can be connected to at least one oxygen source (16), characterized by having at least one measuring system (8,10, 19) for determining at least one parameter of the supplied gas flow, where at least one such measuring system (8,10, 19) influences the control device (12).

12. Device according to one of the Claims 9 to 11, characterized by having at least one measuring system (8, 10, 19) to determine at least one parameter of the supplied gas flow, where at least one such measuring system (8, 10, 19) influences the control device (12) that controls the dosing device (17) for the addition of extra oxygen to the respiratory gas.

13. Device according to one of the Claims 10 to 12, characterized by the fact that at least one such measuring system includes a gas flow meter (8).

14. Device according to one of the Claims 10 to 13, characterized by the fact that at least one such measuring system includes a gas pressure meter (10).

15. Device according to one of the Claims 10 to 14, characterized by the fact that at least one such measuring system includes a device (19) to determine the gas concentration in the gas flow.

16. Device according to one of the Claims 10 to 15, characterized by the fact that at least one such measuring system includes a device (19) to determine the oxygen concentration in the gas flow.

17. Method for supplying a respiratory gas to live organisms (2), characterized by the fact that it determines at least one parameter of the supplied gas and adds a certain amount of oxygen as a function of at least one such measured parameter.

18. Method according to one of the previous Claims, characterized by the fact that a certain amount of oxygen is added after detection of a specified value for at least one such parameter.

19. Method according to one of the previous Claims, characterized by the fact that the addition of a certain amount of oxygen takes place at a certain time after detecting a specified value for at least one such parameter.

20. Method according to one of the previous Claims, characterized by the fact that the addition of a certain amount of oxygen takes place at a certain time after detecting the beginning of an inhalation phase.

21. Method according to one of the previous Claims, characterized by the fact that the addition of a certain amount of oxygen is proportional to the maximum value of the respiratory gas flow and/or the respiratory gas pressure in one breathing cycle.

22. Method according to Claim 21, characterized by the fact that the maximum value of the respiratory gas flow and/or the respiratory gas pressure is determined as the maximum value of the respiratory gas flow and/or the respiratory gas pressure in a previous breathing cycle.

23. Method according to Claim 21 or 22, characterized by the fact that the maximum value of the respiratory gas flow and/or the respiratory gas pressure is determined as the average of the maximum values of the respiratory gas flow and/or respiratory gas pressure of a certain number of prior breathing cycles.

24. Method according to one of the previous Claims, characterized by the fact that the addition of a certain amount of oxygen to the respiratory gas is dependent on the detected value of oxygen concentration in the exhaled gas.

25. Method according to one of the previous Claims, characterized by the fact that the duration of the oxygen supply from the oxygen source (16) is determined depending on the detected value of oxygen concentration in the exhaled gas.

26. Method according to one of the previous Claims, characterized by the use of device according to one of the Claims 1 to 16.

See 3 pages of drawings.

DE 196 26 924 C2

[page left blank]

DRAWINGS PAGE 1

[see source for drawings]

DE 196 26 924 C2

Number: DE 196 26 924 C2

Int. Cl.⁶: A 61 M 16/00

Date of publication: August 19, 1999

DRAWINGS PAGE 2

DE 196 26 924 C2

Number: DE 196 26 924 C2

Int. Cl.⁶: A 61 M 16/00

Date of publication: August 19, 1999

[see source for drawings]

DRAWINGS PAGE 3

DE 196 26 924 C2

Number: DE 196 26 924 C2

Int. Cl.⁶: A 61 M 16/00

Date of publication: August 19, 1999

[see source for drawings]